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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,923	09/16/2003	Eric L. Lien	AM101017	2293
25291	7590	06/06/2006	EXAMINER	
WYETH PATENT LAW GROUP 5 GIRALDA FARMS MADISON, NJ 07940			PRATT, HELEN F	
			ART UNIT	PAPER NUMBER
			1761	

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/663,923	<b>Applicant(s)</b> LIEN ET AL.	
	<b>Examiner</b> Helen F. Pratt	<b>Art Unit</b> 1761	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 13 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 13, 16-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 13, 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (2001/0018197 A1) in view of Lonnerdal.

Wong et al. disclose a method of purifying soy protein by removing ribonucleic acids, phytic acid and phytates from protein material for use in infant formulas (abstract and col. 1, para. (0002, 0019). The reference discloses an amount of 0.43 and 0.18% of phytic acid in a soy isolate composition (page 5, 0048), which is within the claimed range. The reference discloses that the soy mixture is hydrolyzed to reduce the viscosity of the mixture (page 4, 0035). Claims 1-6 differ from the reference in the particular degree of hydrolysis of the soy protein. Lonnerdal discloses that it is known to reduce phytate and to partially hydrolyze the protein in soy formula (title, page 490, and col. 1). The protein can be hydrolyzed to 6.3%, which is within the claimed range. Therefore, it would have been obvious to use degree of hydrolysis of soy protein as disclosed by Lonnerdal in the composition of Wong et al. since Lonnerdal is also making a soy formula for infants.

Claim 13 is to a method for treatment of infants with intolerance to cow milk. However as the method and composition has been shown above. Nothing new is seen in substituting soy

milk for cow's milk, which is well known. Therefore, it would have been obvious to use soy milk in place of cow's milk for cow's milk intolerant infants.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 13-20 are rejected under 35 U.S.C. 102b as being anticipated by Lonnerdal et al. (Am. J. of Clin. Nutri. Cited by applicants).

Lonnerdal et al disclose a soy formula for infants in which the phytate has been removed (page 490, col. 1. ) and the soy protein hydrolyzed. The soy can have 60 mg/L phytate as in claim 1. The degree of hydrolysis is 6.3% as in claims 1-6.

The composition can be used for children with intolerance to cow's milk because of lactose intolerance as in claim 13.

The amounts of phytate have been shown as in claims 16 and 17 and the degree of hydrolysis as in claims 18-20.

**ARGUMENTS**

Applicant's arguments filed 5-18-06 have been fully considered but they are not persuasive. Applicants argue that the reference to Lonnerdal et al. does not disclose feeding a human infant the claimed formula. However, one can see that the study of Lonnerdal was made in order to see how reduced phytate formulas would effect monkeys, and therefore, humans (page 490, col. 2). In fact infant formulas were used in the study (table 1).

Applicants argue that applicants' specification shows that the claimed formula leads to enhanced infant growth. However, the claimed formula would have inherently lead to any growth enhancement since the formula is the same. In addition, this weight gain is not seen in the claims.

Applicants argue as to Wong et al that it is not to a method of feeding infants. However, the reference discloses that the "purpose of the vegetable protein supplement in an infant formula is to increase the nutritional value of the formula..." (col. 1, 0002.). Certainly, then it would have been obvious to combine it with Lonnerdal. Enhancing the infant's growth would have been inherent to the composition.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 571-272-1404. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Milton Cano, can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). 5-31-06

  
**HELEN PRATT**  
**PRIMARY EXAMINER**